



✓ Site: Atlanta, GA

FDAMA STAKEHOLDER MEETING

APRIL 28, 1999

Talking with Stakeholders About FDA Modernization

**Your question/comments will become part of Docket Number: 99N-0386

Fax to: 1-888-361-4011 (on April 28 only)

Title (required) First Name (required) Last Name (required)
☐ Dr. ☐ Mr. Sharon Harris
☒ Mrs. ☐ Ms.
Organization American Red Cross

Stakeholder Group ✓ stakeholder group you represent

☐ Consumer ☐ Consumer Group ☒ Health Professional ☒ Industry ☐ Association ☐ Other

Center ✓ the center/product area your comments address

☐ Center for Biologics ☐ Center for Drug Evaluation and Research
☐ Center for Devices and Radiological Health ☐ Center for Food Safety and Applied Nutrition
☐ Center for Veterinary Medicine ☐ Office of Regulatory Affairs
☐ FDA General

Questions to Stakeholders

Please check the box next to the stakeholder question/s from the March 22, 1999, Federal Register notice which your question/comment addresses.

- ☐ 1. What actions do you propose the Agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decision-making?
- ☐ 2. What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's life cycle?
- ☐ 3. What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decision-making?
- ☐ 4. What actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?
- ☐ 5. What additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?
- ☐ 6. Additional Comments on FDA Modernization Efforts.

YOUR COMMENT/QUESTION

- 1) The annual meeting held in New Orleans with the FDA and the blood manufacturers is very informative and beneficial. Would it be possible to conduct a similar meeting on a local level?
 - 2) What is the plan to expand FDA inspections into transfusion services?
- 99N-0386